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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,379	07/21/2006	Kevin Stamp	7095MH-5	1087
22442	7590	02/23/2009	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			MEDWAY, SCOTT J	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,379	Applicant(s) STAMP, KEVIN	
	Examiner SCOTT MEDWAY	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/30/2008, 9/15/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action based on the 10/579,379 application filed 07/21/2006. Examiner acknowledges the reply filed 10/30/2008.

Claims 1-31 are currently pending and are considered below. Claims 1, 3-11, 15, 17-21, 23-27 and 29-31 have been amended.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-13, 15-17, 19-22 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Crossman et al (U.S. Pat. 5,300,030, hereinafter “Crossman”).

Regarding claims 1-13, 15-17, 19-22, 25 and 29-31, Crossman discloses an injection device comprising: a barrel (18), a needle (22) at one end of the barrel, a plunger (27), an inner housing (8) and an energy source of a spring (14), in communication with the inner housing. Figs. 1-3 of Crossman show the device capable of being moved through three positions, namely a first mode (see Figs. 1 and 2), a second mode (see Figs. 2 and 3) and a third mode (see Figs. 3 and 4). The device additionally has radially flexible rear tags (12) and forward tags (13) which are shown in the figures of Crossman to be substantially T-shaped or L-shaped and fully capable of

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performing the intended use claimed in the instant invention. As to claims 17, there are shown means for allowing the inner housing to move axially forward may be a jugged tooth or notch (11, 16). As to claims 19-22, the needle, barrel and plunger are inherently removable from the device and a needle cover (2, 24, 25) is shown to protect the needle during use. As to claim 25, the needle cover (24) is captive within the tubular extension (25) of the cap (2), where the cap serves as a safety lock to prevent forward movement of the outer housing.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al (U.S. Pat. 5,300,030) in view of Bergens et al (U.S. Pat. No. 6,270,479 B1, hereinafter “Bergens”).

Regarding claim 14, Crossman discloses the invention substantially as claimed except for the energy source being a compressed gas. Bergens discloses an injection device comprising a barrel (121); a needle (123) at one end of the barrel, the needle being moveable in and out of the outer housing (e.g. 110, 112) of the barrel as shown in Figs. 1A and 1B; a plunger mechanism (e.g. 125, 126) with a portion (125) being moveable within the barrel; an inner housing; and an energy source (141) in communication with the inner housing. Bergens discloses the energy source

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comprising compressed gas (col. 8, line 46) (as per claim 14) or a spring (col. 8, line 48). It would have been obvious for one of ordinary skill in the art at the time of the invention to consider substituting a compressed gas source for a spring as taught by Bergens in the device of Crossman, since Bergens teaches that it is well-known to use compressed gas source to drive an injection device, and doing so would provide a more reliable form of forceful injection.

Regarding claim 18, it is noted that Crossman discloses the invention substantially as claimed except for guide means comprising one or more protrusions on the spring. Fig. 3C of Bergens et al shows a guide means (353) having a protrusion as shown on a spring housing (351) and cooperating with a corresponding recess on an interior surface of the outer housing (313) to guide the axial movement of the spring and outer housings. It would have been obvious for one of ordinary skill in the art at the time of the invention to consider attaching guide means to the spring so as to allow the spring to cooperate with corresponding recesses on the outer housing, so as to allow for selective or incremental movement of the spring to improve the accuracy or selectivity of dosage as may be required in use.

5. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al (U.S. Pat. 5,300,030) in view of Sakurai et al (U.S. Pat. 5,211,625, hereinafter "Sakurai").

Regarding claims 23 and 24, it is noted that Crossman discloses the invention as substantially claimed except for a floating rivet intermediate the needle cover and a

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protective rubber sheath. Sakurai discloses a medical device for delivery of treatment fluid to the body, comprising an inner sheath and outer sheath with a nut 97 disposed between them (see Fig. 13). The nut is capable of acting as an insulating member or may additionally be for preventing twisting forces applied to the internal sheath cover to be transmitted to the external sheath. Hence, it would have been obvious for one of ordinary skill in the art at the time of the invention to seek a floating rivet such as a nut suggested by Sakurai, since doing so would provide improved insulation and would be capable of preventing twisting forces transmitted between a needle cover and an outer rubber sheath.

6. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al (U.S. Pat. 5,300,030) in view of Haber et al (U.S. Pat. No. 5,634,906, hereinafter "Haber").

Regarding claims 26-27, it is noted that Crossman discloses the invention substantially as claimed except for a viewing window in the barrel and a viewing window within the outer housing. Haber et al disclose a shield for a dose metering syringe, comprising in Fig. 5 a window (72) located on an outer housing (68) and an inner window (30) located on a barrel 28 (as per claim 26) where medicament is viewed through the two windows, and further, as shown in Fig. 6 of Haber, the two portions are slideable past one another so that the inner housing moves intermediate the viewing window. It would have been obvious to one of ordinary skill in the art at the time of the invention to merely add the windows of Haber to the outer housing and barrel of

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Crossman in order to improve the visibility of medicament within the barrel and to ensure synchronous movement between the outer housing and the barrel during proper use of the device.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al (U.S. Pat. 5,300,030) in view of Bechtold et al (U.S. Pat. No. 5,042,977, hereinafter "Bechtold").

Regarding claim 28, it is noted Crossman discloses the invention substantially as claimed except for a means for emitting an audible indication to a user that the injection is complete. Bechtold discloses an injection device having audible clicking means produced during medication injection (col. 10, lines 12-18), interpreted as including a final click for indicating when injection is complete (as the actuating knob as disclosed is moved to its distal end). It would have been obvious to one of ordinary skill in the art at the time of the invention to outfit the device of Crossman with the audible clicking means of Bechtold, e.g. combining the audible clicking means to one of the spring mechanisms of Crossman, in order to improve the level of dosage achieved and to ensure a patient is aware when a dosage cycle has completed.

Response to Arguments

8. Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/
Examiner, AU 3763
02/14/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

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